UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re INTUNIV ANTITRUST LITIGATION (Both Direct and Indirect Cases)	* * * * * * * * * * *	Civil Action Nos. 16-cv-12653-ADB 16-cv-12396-ADB

MEMORANDUM AND ORDER ON MOTIONS IN LIMINE

BURROUGHS, D.J.

This "pay-for-delay" or "reverse settlement" case arises from an alleged anticompetitive agreement made between the brand and generic manufacturers of Intuniv, an ADHD medication. Defendants Shire LLC and Shire U.S., Inc. (collectively, "Shire") manufacture Intuniv, which is the brand-name for extended release guanfacine hydrochloride. Defendants Actavis Elizabeth LLC, Actavis Holdco US, Inc., and Actavis LLC (collectively, "Actavis" and, together with Shire, "Defendants") manufacture Intuniv's generic counterpart. Plaintiffs, who include both Direct Purchaser Plaintiffs ("DPPs") and Indirect Purchaser Plaintiffs ("IPPs" and, together with DPPs, "Plaintiffs"), allege that they were forced to pay inflated prices for Intuniv because Defendants improperly agreed to delay competition for both brand Intuniv and generic Intuniv in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1–2. See [FWK 140].[1]

[1] For purposes of this Memorandum and Order, the Court refers to docket entries in FWK, et al. v. Shire, et al., 16-cv-12653 as "FWK [ECF No.]" and docket entries in Picone, et al. v. Shire, et al., 16-cv-12396 as "Picone [ECF No.]."

Currently before the Court are multiple motions in limine.[2] [FWK 412; FWK 416; FWK 418; Picone 302 (duplicate of FWK 416); Picone 304 (duplicate of FWK 418)].[3] Each motion is GRANTED in part and DENIED in part.

I. BACKGROUND

In September 2009, the Food and Drug Administration ("FDA") approved Shire's New Drug Application for Intuniv. [FWK 523 at 3]. As a result, Shire was entitled to three years of regulatory exclusivity, during which time the FDA could not approve a generic version of Intuniv. [Id.]. In December 2009, Actavis filed an Abbreviated New Drug Application ("ANDA") for a proposed generic version of Intuniv and asserted that its drug would not infringe on Shire's patent. [Id. at 4]. As the first filer of an ANDA, Actavis would have been entitled to a 180-day period during which only it and Shire could have manufactured generic Intuniv. [Id.].

In May 2010, Shire sued Actavis for patent infringement in the U.S. District Court for the District of Delaware (the "Delaware Court"), which automatically triggered a 30-month stay of the FDA's approval of Actavis' ANDA. [FWK 523 at 4]. After denying Actavis' motion for summary judgment, the Delaware Court held a bench trial in September 2012. [Id. at 5]. While the underlying patent litigation proceeded, Shire and Actavis engaged in settlement negotiations. [Id. at 6–9]. In April 2013, before the Delaware Court issued a decision, Shire and Actavis settled the case. [Id. at 9–10]. In broad strokes, Shire and Actavis agreed that (1) Shire would drop the patent suit, (2) Actavis could make and market generic Intuniv beginning in December

[2] On December 9, 2020, the Court approved the DPPs' settlement with Actavis. [FWK 551]. That settlement did not resolve any claims against Shire or the IPPs' claims against Actavis, though the IPPs informed the Court that they have reached a settlement with Actavis. [FWK 546]. Accordingly, Actavis will not be a party at trial.

[3] For the remainder of the Order, if an identical motion was filed on both dockets, the Court will refer only to the motion filed in FWK, et al. v. Shire, et al., 16-cv-12653.

2014, (3) Actavis would pay a 25% royalty to Shire for the first 180 days that Actavis' generic Intuniv was on the market so long as it was the only generic Intuniv on the market, and (4) Shire could not authorize or license a third party to market or sell a generic Intuniv during Actavis' 180-day exclusivity period but could, itself or via an affiliate, market a generic Intuniv during that time. [Id. at 10].

Plaintiffs argue that this settlement agreement was anticompetitive. See [FWK 247]. According to Plaintiffs, the market for Intuniv would have become competitive earlier had Shire and Actavis not entered into their settlement because Actavis would have launched a generic Intuniv before December 2014 and Shire would have authorized a third-party to market a generic to compete with Actavis' generic. [Id. ¶¶ 151–54]. More specifically, Plaintiffs argue that as part of the settlement, Shire and Actavis agreed that Shire would not release its own authorized generic ("AG") during Actavis' 180-day exclusivity period (the "no-AG Agreement") in exchange for Actavis waiting until December 2014 to enter the market. This purported "reverse payment," delayed entry date in exchange for the no-AG Agreement, is the crux of Plaintiffs' case. See [id. ¶ 2].

II. DISCUSSION

A. FWK 412: Plaintiffs' Omnibus Motion in Limine

In their omnibus motion in limine, Plaintiffs make twenty-six discrete motions. [FWK 412]. The Court addresses each in turn.

1. Plaintiffs' Motion in Limine No. 1

Plaintiffs seek an order requiring Defendants to make available, for Plaintiffs' case-in-chief, any witnesses whom Defendants also intend to call at trial. [FWK 412 at 1]. Plaintiffs argue that it would be unfair to have to rely on videotaped deposition testimony for

certain witnesses if those same witnesses are going to provide live testimony on Defendants' behalf. [FWK 421-1 at 12]. Defendants respond that they intend to work with Plaintiffs to ensure that all their witnesses are available but maintain that some witnesses, including former employees who are outside of the Court's 100-mile subpoena range, are not within their control and that, in any event, the Court lacks authority to require Shire to produce non-party witnesses for Plaintiffs. [FWK 426-1 at 13].

The Court appreciates Defendants' willingness to work cooperatively with Plaintiffs to secure access to witnesses and encourages both sides to make efforts to reasonably resolve witness issues. As additional guidance, for efficiency and the convenience of witnesses, the Court does not anticipate any witness testifying twice. Therefore, if there are witnesses that will be called by both sides, the parties should work out when they will testify. In those situations, the witness will testify out of order for one side or the other, but each side will be able to conduct a direct examination and cross-examination during that witness's single appearance. The Court expects that Defendants will facilitate the appearance of employee witnesses and other witnesses within their control. For witnesses that have travel restrictions as a result of COVID, the Court will help to arrange for live remote video testimony. The Court will not require Defendants to produce witnesses that are not under their control or that are equally available to both sides.

2. Plaintiffs' Motion in Limine No. 2

Plaintiffs move to exclude evidence of any party's size or financial condition, arguing that the relative wealth or financial condition of parties or members of the DPP class are irrelevant and unduly prejudicial. [FWK 412; FWK 421-1 at 12–13]. Defendants assert that Plaintiffs' motion is overbroad and that the Court should decide whether specific evidence is unduly prejudicial at trial. [FWK 426-1 at 14].

The Court accepts Defendants' representation that they will not seek to elicit, or affirmatively present, overly prejudicial or irrelevant evidence concerning the parties' size and/or wealth. See [FWK 426-1 at 14 (representation)]. That said, the Court will address appropriate relevance and prejudice objections at trial.

3. Plaintiffs' Motion in Limine No. 3

Plaintiffs move to exclude self-serving portions of patent litigation transcripts. [FWK 412 at 1]. They argue that the hearsay exception found in Federal Rule of Evidence 804(b)(1) is inapplicable because Plaintiffs did not have the opportunity to cross-examine witnesses at the patent trial. [FWK 421-1 at 13–14]. Defendants assert that the transcripts are admissible because they will be offered for a non-hearsay purpose (i.e., effect on the listener); that they constitute Plaintiffs' experts' adoptive admissions; and that because Plaintiffs' experts relied on them, Defendants must be able to introduce other portions to rebut that expert testimony. [FWK 426-1 at 14–17].

The Court will address the admissibility of specific portions of the patent litigation transcript at trial. The Court notes, however, that Plaintiffs are correct regarding the difference between the admissibility of the transcripts and the use of the transcripts for other purposes. See [FWK 434-1 at 10]. During cross-examination, Defendants may attempt to undermine Plaintiffs' experts' testimony by confronting them with portions of the patent litigation transcript that do not support their opinions or by seeking to impeach them with their purportedly inconsistent prior statements. Using the transcripts for these purposes, however, does not transform otherwise inadmissible hearsay into admissible evidence. To independently introduce portions of the patent litigation transcript into evidence, Defendants will have to demonstrate that a hearsay exception applies or that the portion that they seek to admit is not, in fact, hearsay.

4. Plaintiffs' Motion in Limine No. 4

Plaintiffs move to exclude cumulative expert testimony, arguing that, insofar as Shire's experts will offer testimony that is duplicative of testimony to be offered by Actavis' experts, or vice versa, only one expert should be permitted to testify. [FWK 412 at 1; FWK 421-1 at 14–15]. Defendants assert that there will not be duplicative testimony and that, in any event, the Court should not decide whether testimony is duplicative prior to trial. [FWK 426-1 at 17–18].

Because Actavis will not be a party when this case is tried, see [FWK 551 (order approving Actavis' settlement with DPPs); FWK 546 (letter indicating that Actavis has settled with IPPs)], Plaintiffs' concern that there will be duplicative testimony from Shire's and Actavis' experts is moot. Further, Court will not exclude testimony as duplicative prior to trial. At trial, Plaintiffs may object to testimony as a waste of time or needlessly cumulative under Federal Rule of Evidence 403.

5. Plaintiffs' Motion in Limine No. 5

Plaintiffs seek to exclude evidence that they failed to mitigate damages. [FWK 412 at 1]. They argue that antitrust plaintiffs have no duty to mitigate and, therefore, evidence regarding mitigation or lack thereof would be irrelevant. [FWK 421-1 at 15]. Defendants agree that Plaintiffs were not required to mitigate damages but maintain that Plaintiffs' request to exclude "mitigation evidence" is overbroad because, if granted, it would serve to exclude evidence that is relevant for other reasons. [FWK 426-1 at 18–19].

The parties agree that Plaintiffs had no duty to mitigate damages, and Defendants will therefore be precluded from introducing evidence that they did not do so. The Court will rule on the relevance and admissibility of other, mitigation-adjacent evidence (e.g., how quickly

Plaintiffs switched to purchasing generic Intuniv or another ADHD drug) as those issues arise at trial.

6. Plaintiffs' Motion in Limine No. 6

Plaintiffs move to exclude mention of "downstream effects." [FWK 412 at 1]. Defendants agree that they cannot introduce evidence that the DPPs' damages should be reduced because they passed on any overcharges to downstream customers, but maintain that general evidence regarding how the pharmaceutical market functions must be admitted because it is relevant to issues such as market power. [FWK 426-1 at 19–20].

Defendants cannot introduce evidence regarding whether the DPPs here passed along any portion of the alleged overcharge to their downstream customers. Beyond that, the Court will determine the admissibility of other "downstream" evidence at trial.

7. Plaintiffs' Motion in Limine No. 7

Plaintiffs move to exclude the mention of treble damages or attorneys' fees. [FWK 412 at 1]. Plaintiffs argue that if the jury is made aware of the potential for treble damages or attorneys' fees, it may impermissibly reduce an award to account for those factors. [FWK 421-1 at 16]. Defendants state that they will not refer to "special damages recoverable under the Sherman Act," but maintain that a blanket ruling precluding them from referring to fees and special damages is overbroad because, among other things, it would prevent Defendants from accurately describing the magnitude of Actavis' exposure to an adverse outcome in the underlying patent litigation following an at-risk launch. [FWK 426-1 at 20].

The parties agree that Defendants cannot introduce evidence regarding Plaintiffs' potential recovery of treble damages and attorneys' fees if they prevail in this litigation, and

Defendants will therefore be precluded from doing so. The Court will rule on other references to fee awards and multiple damages as the issue arises at trial.

8. Plaintiffs' Motion in Limine No. 8

Plaintiffs move to exclude argument that the reverse payment is immune from antitrust scrutiny because it predated the Supreme Court's ruling in FTC v. Actavis. [FWK 412 at 1]. Defendants state that they do not intend to argue that they are immune from antitrust liability but maintain that they must be allowed to present testimony about the state of the law when they entered into their settlement agreement to rebut Plaintiffs' implicit no-AG agreement argument. [FWK 426-1 at 20–22].

Given Defendants' position, Plaintiffs' motion is moot. The Court does not understand Plaintiffs' motion as seeking to bar Defendants from discussing the state of the law when the settlement was reached or the impact, if any, that Actavis had on antitrust law. [FWK 421-1 at 16–17]. To the extent Plaintiffs do seek such a ruling, they may object to argument and/or evidence at trial.

9. Plaintiffs' Motions in Limine Nos. 9–13

Plaintiffs seek five orders preventing Defendants from advancing various purportedly procompetitive justifications for their allegedly anticompetitive conduct. [FWK 421-1 at 17–28]. Specifically, Plaintiffs argue that the procompetitive justifications they seek to preclude are not legally cognizable because they do not justify the no-AG Agreement. [Id. at 17–18]. Further, Plaintiffs assert that Defendants carry the burden of demonstrating that the alleged restraint is necessary to achieve the procompetitive goal and proving that the restraint is the least restrictive means of achieving that goal. [Id. at 18–19]. Defendants respond that Plaintiffs' focus on the specific aspect of the settlement agreement that they view as anticompetitive, the alleged no-AG

Agreement, is misplaced and that antitrust defendants in reverse payment cases are routinely permitted to assert procompetitive justifications arising from a settlement agreement as a whole. [FWK 426-1 at 22–23]. Defendants also maintain that Plaintiffs have misstated the burden-shifting process. [Id. at 23–24].

In a reverse payment case, the Court applies the rule of reason. First, Plaintiffs must "'prove anticompetitive effects,' by demonstrating 'a payment for delay, or, in other words, payment to prevent the risk of competition.'" In re Loestrin 24 Fe Antitrust Litig. ("Loestrin I"), 261 F. Supp. 3d 307, 329 (D.R.I. 2017) (quoting King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 412 (3d Cir. 2015)). In assessing whether the payment had anticompetitive effects, the Court must consider "its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." Id. (quoting Fed. Trade Comm'n v. Actavis, 570 U.S. 136, 159 (2013)). Once Plaintiffs have demonstrated such a payment, the burden shifts to Defendants "to show that [the] challenged payment was justified by some procompetitive objective." Id. (quoting In re Nexium (Esomeprazole) Antitrust Litig., 42 F. Supp. 3d 231, 262–63 (D. Mass. 2014)). If Defendants make such a showing, the burden then shifts once again to Plaintiffs to establish that the deal's anticompetitive effects outweigh its procompetitive benefits. Id.

Despite Plaintiffs' contention, Defendants are not limited to asserting procompetitive justifications for the alleged no-AG Agreement specifically. In re Loestrin 24 Fe Antitrust Litig. ("Loestrin II"), 433 F. Supp. 3d 274, 317 (D.R.I. 2019) (declining to adopt the narrow approach of requiring defendants to offer procompetitive justifications for the payment specifically as opposed to the settlement agreement generally); In re Solodyn (Minocycline Hydrochloride)

Antitrust Litig., No. 14-md-02503, 2018 WL 734655, at *4 (D. Mass. Feb. 6, 2018) (same); see In re Lidoderm Antitrust Litig., No. 14-md-02521, 2018 WL 7814761, at *2 (N.D. Cal. Feb. 7, 2018) (same). Further, the Court has already found that there remains a material dispute of fact as to the existence of the no-AG Agreement. [FWK 523 at 43]. It will not now restrict Defendants to offering procompetitive justifications only for an agreement that they argue does not exist.

Against this backdrop, the Court addresses each of Plaintiffs' specific requests.

a. Plaintiffs' Motion in Limine No. 9

Plaintiffs seek to prevent Defendants from asserting aversion to litigation risk as a procompetitive justification, arguing that risk aversion is not a cognizable procompetitive justification for the no-AG Agreement. [FWK 412 at 1; FWK 421-1 at 20–23]. Defendants maintain that Plaintiffs' motion is overbroad and, if granted, would exclude evidence that they should be permitted to introduce. [FWK 426-1 at 24–26].

Based on Defendants' response, it appears to the Court that the anticipated expert testimony Plaintiffs seek to exclude, see [FWK 421-1 at 20–21], will not be offered as a procompetitive justification but rather as evidence that the alleged no-AG Agreement did not, in fact, exist, see [FWK 426-1 at 25]. The Court will deny this motion with leave to renew at trial depending on the context in which the testimony is offered.

In the hopes of facilitating agreement between the parties as to proposed testimony and forestalling objections during trial, the Court notes the following. First, Defendants are entitled to dispute the existence of a no-AG agreement and in so doing may, among other things, introduce evidence as to why settlement might be preferable to continuing patent litigation. Second, as discussed above, Defendants may assert procompetitive justifications for the

settlement as a whole, rather than being limited to procompetitive justifications solely for the no-AG Agreement. See Solodyn, 2018 WL 734655 at *4. Third, averting litigation risk is not, in and of itself, procompetitive unless it benefits the market and/or consumers as opposed to just the parties. See Lidoderm, 2018 WL 7814761 at *6–7.

b. Plaintiffs' Motion in Limine No. 10

Plaintiffs move to preclude Defendants from arguing or offering evidence that the no-AG Agreement was justified because the settlement agreement provided for an entry date that preceded patent expiry. [FWK 412 at 1]. They assert that, under Actavis, "early entry" cannot be a procompetitive justification for a settlement. [FWK 421-1 at 23–25]. Defendants maintain that Plaintiffs again focus too narrowly on the no-AG Agreement, as opposed to the settlement as a whole, and further that courts routinely permit antitrust defendants to offer early entry as a procompetitive justification. [FWK 426-1 at 27–28].

Plaintiffs misconstrue Actavis. In that case, the Supreme Court did not hold that early entry can never be offered as a procompetitive justification. Rather, the court merely held that early entry does not *per se* justify a reverse payment and that reverse payment settlements can, under certain circumstances, violate antitrust laws. Actavis, 570 U.S. at 141; Solodyn, 2018 WL 734655, at *5 (noting that the Actavis court "rejected the proposition that early generic entry *per se* justified a reverse payment"). In fact, the Supreme Court specifically noted that "settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition." Actavis, 570 U.S. at 154. Consistent with Actavis, multiple courts have permitted antitrust defendants to present evidence regarding early entry because it is relevant to the procompetitive justification analysis. See Solodyn, 2018 WL 734655, at *5 ("[T]he [c]ourt is satisfied that at least from the perspective of Impax, the generic manufacturer

here, early entry may be relevant to the inquiry. This testimony is thus admissible as to Impax's procompetitive justifications for entering into these agreements with Medicis."); Lidoderm, 2018 WL 7814761, at *7 ("In these circumstances, 'early' entry as judged simply by the length of the now-not-challenged patent cannot be the sole procompetitive justification, but it can—if supported by objective testimony—be part of that analysis.").

c. Plaintiffs' Motion in Limine No. 11

Plaintiffs move to exclude evidence regarding Defendants' purported research and development ("R&D") activities and high fixed costs, arguing that testimony regarding the social benefits of exclusivity in the pharmaceutical industry is not a cognizable antitrust defense and would be confusing and prejudicial. [FWK 412 at 1; FWK 421-1 at 25–26]. Defendants respond that they do not intend to offer evidence of R&D and fixed costs to show procompetitive activity, but may refer to R&D and other costs for other purposes. [FWK 426-1 at 28–29].

The Court accepts the Defendants' representations. They will be permitted to offer evidence, where appropriate, regarding R&D and fixed costs for purposes other than showing pro-competitiveness. For instance, the Court has already determined that Dr. Bell will be permitted to offer testimony as to why marginal cost may not be as probative of market power in a pharmaceutical case as it is in other cases due to high fixed costs in the pharmaceutical industry. See [FWK 525 at 9].

d. Plaintiffs' Motion in Limine No. 12

Plaintiffs seek to exclude testimony by Actavis executives to the effect that an AG launch is tantamount to "stealing" from the first-to-file generic manufacturer or that the first-to-file generic manufacturer is "entitled" to no competition from an AG during its first 180 days.

[FWK 412 at 2]. Plaintiffs argue that such testimony is "contrary to law, invites jury nullification, and would be unduly prejudicial." [FWK 421-1 at 26–27].

Because Actavis will not be a party when this case is tried, see [FWK 551 (order approving Actavis' settlement with DPPs); FWK 546 (letter indicating that Actavis has settled with IPPs)], Plaintiffs' concern that Actavis executives will offer impermissible testimony may well be moot. If they do testify, they will be permitted to testify regarding their motivations for entering into the original settlement agreement, including their understanding that generic manufacturers are generally afforded a 180-day exclusivity period after filing an ANDA. Whether Shire and Actavis entered into a no-AG Agreement is a key issue in this case, and Actavis' views about AG competition may be relevant as to whether such an agreement was reached. At trial, Plaintiffs may clarify that the 180-day exclusivity period does not foreclose the brand manufacturer from releasing an AG and/or seek an instruction from the Court regarding the bounds of the Hatch-Waxman Act.

e. Plaintiffs' Motion in Limine No. 13

Plaintiffs move to exclude testimony that a no-AG promise is an exclusive patent license. [FWK 412 at 2]. They argue that the term "exclusive license' is a euphemism intended to mask the unlawful no-AG Agreement. [FWK 421-1 at 27–28]. Defendants maintain that "exclusive license" is a legally accurate phrase and that Defendants should not be forced to use Plaintiffs' preferred terminology. [FWK 426-1 at 30–31].

As a general matter, litigants are entitled to present their own theories of the case, including choosing their own language. The Court will not require Defendants to conform to Plaintiffs' favored terminology, especially in light of the fact that Defendants dispute the existence of the no-AG Agreement. Further, describing a no-AG Agreement as an exclusive

license "does not imply it is legal or otherwise protected from anti-trust scrutiny." Lidoderm, 2018 WL 7814761 at *8. That said, depending on context, Plaintiffs may object to Defendants describing the exclusive license as "authorized" or otherwise implying that it is *per se* lawful or otherwise shielded from antitrust scrutiny.

10. Plaintiffs' Motion in Limine No. 14

Plaintiffs ask to exclude argument to the effect that Shire's reverse payment was not "large" because it represented only a small percentage of Shire's profits. [FWK 412 at 2]. Plaintiffs argue that the determination as to whether a payment is "large" is contingent upon anticipated saved litigation costs and therefore comparing it to Shire's profits is irrelevant and prejudicial. [FWK 421-1 at 28–31]. Defendants maintain that whether a payment is "large" is a jury question and that the jury is entitled to consider multiple factors, including the relationship between the payment at issue and profits. [FWK 426-1 at 31–34].

First, nothing in Actavis suggests that, in deciding whether a payment is "large," a jury cannot consider the defendant's profits. In fact, the court suggests that the value of the patent, which is related to the profits generated by the patented product, is relevant in considering the size of the payment. Actavis, 570 U.S. at 157–58. Additionally, other courts in this circuit have denied similar motions in limine. See Order on Pending Motions in Limine at 5, In re Loestrin 24 Fe Antitrust Litig., No. 13-md-02472 (D.R.I. Dec. 6, 2019), ECF No. 1362 ("The jury will evaluate the size and justifications for the settlement in its factual context, including the business reasons for it."); Court's Rulings on Various Motions In Limine, In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14-md-02503 (D. Mass. Mar. 8, 2018), ECF No. 1089 (noting that "whether a reverse payment was 'large and unjustified,' requires viewing the payment in its factual context, which may include certain business realities" (citations omitted)).

Because the jury is entitled to decide whether the alleged payment was large in context, the Court will not prohibit Defendants from offering evidence regarding Shire's profits.

11. Plaintiffs' Motion in Limine No. 15

Plaintiffs move to exclude evidence of therapeutic interchangeability because Defendants do not have a physician expert witness. [FWK 412 at 2; FWK 421-1 at 31–32].

The Court has already ruled on the extent to which Dr. Bell will be permitted to testify regarding interchangeability. See [FWK 525 at 11].

12. Plaintiffs' Motion in Limine No. 16

Plaintiffs ask that Defendants' expert Dr. Bell be precluded from offering evidence purporting to reflect non-price competition, arguing that such evidence is irrelevant to determining the relevant market because the relevant market is defined by the cross-elasticity of demand, which is a factor of price. [FWK 412 at 2; FWK 421-1 at 32–33].

The Court has already ruled on Dr. Bell's non-price competition testimony. See [FWK 525 at 8–11]. Plaintiffs may cross examine Dr. Bell regarding his methods.

13. Plaintiffs' Motion in Limine No. 17

Plaintiffs move to exclude Dr. Bell's "own price elasticity" analysis, claiming that "own price elasticity" is irrelevant to determining market power and is likely to confuse the jury. [FWK 412 at 2; FWK 421-1 at 33–34].

The Court has already addressed Dr. Bell's price elasticity analysis. See [FWK 525 at 8–11]. Plaintiffs may question Dr. Bell as to his analysis during cross-examination.

14. Plaintiffs' Motion in Limine No. 18

Plaintiffs seek the exclusion of expert testimony that Shire's gross profits are reduced by sunk costs, asserting that factoring R&D and other costs into gross profits is "analytically incorrect" and "inconsistent with industry practice." [FWK 412 at 2; FWK 421-1 at 34–35].

Assuming it was adequately disclosed, whether Defendants' expert's opinion is "analytically incorrect," "inconsistent with industry practice," [FWK 421-1 at 35], or a "generalized statement[]" with insufficient record support, [FWK 434-1 at 21], is a question of weight not admissibility, and the Court will therefore not exclude such opinions.

15. Plaintiffs' Motion in Limine No. 19

Plaintiffs ask that Shire be precluded from arguing or offering evidence concerning its purported post-settlement evaluation of a potential AG launch, on the basis that Shire is invoking attorney-client privilege to selectively disclose helpful materials related to its evaluation of an AG launch but withholding harmful ones. [FWK 412 at 2; FWK 421-1 at 35–39]. Shire maintains that it has not waived privilege and intends to introduce only non-privileged evidence of its post-agreement evaluation of an AG launch. [FWK 426-1 at 36].

Although Plaintiffs state in their reply brief that they currently seek exclusion rather than a finding of waiver, [FWK 434-1 at 21 n.60], the Court views the issues as inextricably intertwined. As an initial matter, the Court has not seen the documents that Plaintiffs claim are privileged and therefore cannot independently evaluate whether those documents are, in fact, privileged. The Court does note that marking a document "privileged" does not make it so. In the First Circuit, that "the attorney-client privilege is highly valued" is an "unarguable proposition." In re Keeper of Records, 348 F.3d 16, 23 (1st Cir. 2003). For that reason, "courts should be cautious about finding implied waivers," and "[c]laims of implied waiver must be

evaluated in light of principles of logic and fairness." Id. "An 'at issue' waiver occurs when a party injects certain claims or defenses into the case which implicate, *i.e.*, put 'at issue' the communications of counsel." Bacchi v. Mass. Mut. Life Ins. Co., 110 F. Supp. 3d 270, 275 (D. Mass. 2015) (citing Clair v. Clair, 982 N.E.2d 32, 43–44 (Mass. 2013)). "The classic example is where a defendant defends itself [by asserting] that it relied on the advice of counsel . . . [because] the defendant voluntarily puts its attorney's advice at issue and fairness dictates that the opposing party should be able to discover all of the attorney's communications on the particular subject, not just the advice that is helpful to the defendant." Id. "[M]erely pleading a good faith defense does not by itself waive privilege." Id. "[T]here is no waiver if the defendant intends to establish its good faith defense by showing that its conduct was actually lawful, or was actually approved by regulators, and does not intend to rely on counsel's opinion or advice." Id. at 277.

On the record before it, the Court cannot find that Shire has implicitly waived privilege, though it will not foreclose the possibility of finding that there is a waiver if, for example, Shire unfairly and selectively relies on privileged materials or attempts to withhold communications that would provide context necessary to avoid misleading the factfinder. Plaintiffs' theory of the case seems to be that the settlement agreement between Shire and Actavis contained an implicit no-AG Agreement notwithstanding the fact that the written agreement explicitly afforded Shire the right to launch its own AG. To refute that theory, Shire intends to introduce evidence that, after the settlement, it did, in fact, evaluate the possibility of launching its own AG. That lawyers were involved in this process does not necessarily put those lawyers' opinions at issue in this case. See Bacchi, 110 F. Supp. 3d at 275 (noting that at-issue waiver occurs when a party injects defenses into a case which implicate the communications of counsel). Because the

attorney-client privilege applies to communications, not conduct, Shire may introduce evidence of *actions* it took without waiving the attorney-client privilege so long as it does not present evidence of the legal advice it received before taking those actions.

Plaintiffs argue that Shire has withheld complete disclosure, [FWK 421-1 at 35–36], but litigants routinely produce, and rely upon, non-privileged documents concerning a given topic and withhold privileged documents on the same topic. The rules of discovery do not require "complete disclosure" and parties are entitled to withhold privileged materials. Further, the case that Plaintiffs primarily rely upon does not compel a different conclusion. In Lidoderm, the antitrust defendant put its subjective beliefs regarding its intention to launch an AG at issue and, because it formed that subjective belief based on attorney advice, the court ruled that the defendant would have to choose between being precluded from relying on that specific subjective belief and waiving privilege on the topic. In re Lidoderm Antitrust Litig., No. 14-md-02521, 2016 WL 4191612, at *2 (N.D. Cal. Aug. 9, 2016).

Accordingly, the Court will not, at this time, preclude Shire from presenting argument and evidence concerning its post-settlement evaluation of a potential AG launch. Should Shire put attorney advice at issue, Plaintiffs may renew their request for preclusion or a finding of waiver. Further, Plaintiffs may seek to characterize Shire's evaluation as illusory by, among other things, emphasizing that launching its own AG would be inconsistent with industry practice and highlighting the timing of the purported evaluation.

16. Plaintiffs' Motion in Limine No. 20

Plaintiffs seek to exclude expert testimony from Mr. Galbraith concerning Judge Andrews' statements from the bench, his capabilities, and his state of mind, arguing that such testimony would be speculative and unduly prejudicial. [FWK 412 at 2; FWK 421-1 at 39–40].

Just as Professor Thomas will be permitted to testify as to his professional opinion regarding the outcome of the patent litigation, see [FWK 525 at 24], so too will Mr. Galbraith. To the extent Plaintiffs believe that Mr. Galbraith is selectively relying upon favorable portions of the patent litigation record, misconstruing Judge Andrews' questions, or otherwise offering inappropriate testimony—including testimony that is speculative or conjectural—they may object or seek to undermine his testimony during cross-examination.

17. Plaintiffs' Motion in Limine No. 21

Plaintiffs move to exclude testimony by Mr. Murthy and Mr. Patel about how Shire could have launched an AG without a generic product distributor, asserting that such testimony is speculative, likely to mislead the jury, and unduly prejudicial. [FWK 412 at 2; FWK 421-1 at 40–42].

The Court has already ruled on this aspect of Mr. Murthy's testimony. See [FWK 525 at 34–35].

As to Mr. Patel, given that he is Actavis' expert witness, and Actavis will not be a party at trial, see [FWK 551; FWK 546], Plaintiffs' objection may well be moot. If Mr. Patel does testify, he will be permitted to offer his opinion as to what a reasonable company in Actavis' shoes would have believed about Shire's capacity to launch its own AG. Plaintiffs may then endeavor to undermine Mr. Patel's testimony on cross-examination.

18. Plaintiffs' Motion in Limine No. 22

Plaintiffs move to exclude Mr. Murthy's expert testimony about the factors a brand company would consider in deciding whether to launch an AG. [FWK 412 at 2]. They argue that Mr. Murthy's testimony is speculative and has not been applied to the facts of the case. [FWK 421-1 at 42–43]. Defendants maintain that the testimony is not speculative and that

Plaintiffs' own expert acknowledged that the factors Mr. Murthy identified are among those typically considered. [FWK 426-1 at 47–49].

The Court has already ruled on this aspect of Mr. Murthy's testimony. See [FWK 525 at 30–35]. During cross-examination, Plaintiffs may question Mr. Murthy concerning the factors that he has identified and their applicability to this case.

19. Plaintiffs' Motion in Limine No. 23

Plaintiffs seek to exclude Mr. Zoffer's legal interpretation of the settlement agreement because legal analysis is not a permissible subject of expert testimony. [FWK 412 at 2; FWK 421-1 at 43–44]. Defendants maintain that Mr. Zoffer is simply rebutting Plaintiffs' experts' opinions and, further, that he will be assessing the contract terms in light of industry custom and practice rather than offering a purely legal opinion regarding contract construction. [FWK 426-1 at 49–50].

The Court has already ruled on this aspect of Mr. Zoffer's testimony. See [FWK 525 at 39–41].

20. Plaintiffs' Motion in Limine No. 24

Plaintiffs move to preclude Professor Klibanov's expert testimony concerning commercial success, arguing that Professor Klibanov, a chemist, cannot opine regarding commercial success and should not be permitted to repeat the opinions of Defendants' economist experts. [FWK 412 at 2; FWK 421-1 at 44–46].

The Court has already ruled on this aspect of Professor Klibanov's testimony. See [FWK 525 at 18–21].

21. Plaintiffs' Motion in Limine No. 25

Plaintiffs move to exclude argument and evidence that following the Federal Circuit's review of Judge Andrews' rulings, it would have reversed Actavis' trial win and ordered a new trial that Shire would have won. [FWK 412 at 2–3]. They argue that such argument would be speculative and more prejudicial than probative. [FWK 421-1 at 46–47].

As discussed, supra, Section II.A.16, Mr. Galbraith will be permitted to testify as to his professional opinion regarding the outcome of the patent litigation, including a possible appeal. Plaintiffs' objections go to the weight rather than the admissibility of such testimony. At trial, Plaintiffs may object where appropriate and cross examine Mr. Galbraith on the bases for his opinions.

22. Plaintiffs' Motion in Limine No. 26

Plaintiffs move to exclude evidence and argument regarding the opioid crisis, bankruptcy, or other past or present litigation involving Plaintiffs (and Rochester Drug Co-Operative, Inc. ("RDC") in particular) on the basis that such evidence and argument is irrelevant and would be unduly prejudicial. [FWK 412 at 3; FWK 421-1 at 47–51]. Defendants state that they do not intend to introduce any evidence regarding bankruptcy or unrelated antitrust litigations, provided that Plaintiffs agree to the same. [FWK 426-1 at 52]. As to evidence of RDC's past dishonest or criminal conduct, Defendants maintain that such evidence can be used to attack RDC's credibility. [Id.].

Given the parties' agreement, no evidence or argument regarding bankruptcy and/or unrelated antitrust litigations involving the parties will be permitted. Because RDC is no longer the DPP class representative, the Court assumes that Defendants no longer intend to attack

RDC's credibility. Should that not be the case, or should circumstances change before trial, the Court will rule at trial on the use of evidence regarding RDC's past misconduct.

B. FWK 418: Defendants' Omnibus Motion in Limine

In their omnibus motion in limine, Defendants make twenty-two separate motions, [FWK 418], which the Court addresses individually below.

1. Defendants' Motion in Limine No. 1

Defendants move to preclude Plaintiffs from impugning Defendants' intentions or implying bad faith based on legal developments that post-date the settlement. [FWK 418 at 1]. They argue that Actavis represented a significant change in antitrust law and that Plaintiffs should be prohibited from using a case from June 2013 to suggest that conduct in April 2013 was undertaken in bad faith. [FWK 419-1 at 17–19]. Plaintiffs respond that Actavis did not change the law and that Defendants are attempting to end-run the doctrine of retroactive operation of judicial decisions. [FWK 430-1 at 14–17].

As discussed supra, Section II.A.8, the parties agree that Defendants cannot argue that they are immune from antitrust liability because the settlement at issue in this litigation happened before the Supreme Court's Actavis ruling. By the same token, Plaintiffs cannot use the Supreme Court's Actavis decision, which was issued in June 2013, to suggest that Defendants were acting in bad faith when they executed their settlement in April 2013. Both parties may, however, offer argument and evidence regarding the state of antitrust law at the time of the settlement insofar as it is relevant to the key issue in this case: whether there was a no-AG agreement. Plaintiffs may present evidence and argument to the effect that, given the state of the law at the time, Defendants would have known that an explicit no-AG agreement would have been unlawful and so resorted to an implicit no-AG agreement as part of their settlement

agreement. Defendants may then argue that an explicit no-AG agreement was not necessarily unlawful at the time and therefore they would have had no reason to enter into an implicit no-AG agreement. If Plaintiffs believe Defendants are seeking to immunize themselves from antitrust liability because Actavis post-dates the settlement or if Defendants believe Plaintiffs are trying to imply that Defendants acted in bad faith based on Actavis, the aggrieved parties may renew their objections at trial.

2. Defendants' Motion in Limine No. 2

Defendants seek to prevent Plaintiffs from advancing a theory of liability based solely on Shire's agreement not to launch an AG using a third party, arguing that Plaintiffs did not adequately plead this theory and have no evidence to support it. [FWK 418 at 1; FWK 419-1 at 20–23]. Plaintiffs maintain that they cured any pleading deficiencies in their second amended complaint and that there is ample record evidence to allow this theory to reach the jury. [FWK 436-1 at 13–14].

Contrary to Plaintiffs' assertions, the allegations in the second amended complaint that they cite do not state an independent theory of liability. Rather, they make clear that an agreement not to launch an AG using a third party is only unlawful insofar as it is actually an agreement to not launch an AG at all. See [FWK 247 ¶ 186 ("This no-third-party AG agreement between Shire and Actavis, standing alone, constitutes an unlawful agreement . . . *because it functions as a no-AG agreement*" (emphasis added)); id. ¶ 200 ("Actavis understood the practical consequences of the no third-party AG agreement—that Shire would lack the capacity to distribute an AG Intuniv, and that *the no third-party agreement would function as a no-AG agreement*" (emphasis added)); id. ¶ 201 ("As a practical consequence of entering into an agreement to eliminate third-party distribution of an authorized generic, Shire and Actavis

entered into an unlawful no-AG agreement.")]. Further, the expert opinions cited by Plaintiffs confirm that the no-third-party AG agreement is relevant only to the extent that it demonstrates that Defendants entered into a no-AG Agreement. See [FWK 430-1 at 19 (citing expert opinion that "the agreement *functionally results* in a no-AG commitment on the part of Shire" (emphasis added))]. Plaintiffs will be permitted to make arguments and offer evidence concerning the fact that, under the circumstances, the no-third-party AG agreement suggests the existence of an unlawful no-AG agreement but will be precluded from arguing that the no-third-party AG agreement within the settlement agreement is, itself, violative of the Sherman Act.

3. Defendants' Motion in Limine No. 3

Defendants move to keep Plaintiffs from introducing "second guessing" evidence of a purported anticompetitive conspiracy. [FWK 418 at 1]. In support, Defendants argue that much of the evidence that Plaintiffs intend to introduce to demonstrate the existence of the no-AG Agreement is deficient as a matter of law and should be excluded. [FWK 419-1 at 23–28]. Plaintiffs maintain that the evidence they will seek to admit is permissible and, further, even if some of it is not, the Court should defer ruling on it until trial. [FWK 430-1 at 19–23].

The Court has already found that there is a material dispute as to whether a no-AG Agreement exists. See [FWK 523 at 43]. At trial, each side will no doubt present evidence regarding that critical question. The Court will rule on objections as to particular pieces of evidence at trial. The Court, however, now provides the following guidance. Defendants' business decisions are not sacrosanct and may be challenged by Plaintiffs at trial. The jury will then decide whether the evidence Plaintiffs have presented is sufficient to impose liability under

the law as provided by the Court.[4] If Defendants believe that Plaintiffs have not adduced sufficient evidence, they may move for a directed verdict at the appropriate time.

4. Defendants' Motion in Limine No. 4

Defendants seek to prevent Plaintiffs from referring to or admitting Federal Trade Commission ("FTC") statements, publications, and other documents because such materials would bias the jury against them by creating the impression that all reverse payments are unlawful. [FWK 418 at 1]. They further aver that Plaintiffs should not be allowed to cloak themselves with the authority of the FTC, that much of the evidence that Plaintiffs seek to admit is hearsay, and that, if the Court permits the admission of FTC materials, Defendants must be permitted to present evidence that the FTC declined to pursue enforcement against them. [FWK 419-1 at 28–33]. Plaintiffs respond that the FTC materials it seeks to admit are relevant and admissible as public records, and that the fact that the FTC did not pursue enforcement action is not probative of the lawfulness of the settlement agreement at issue here. [FWK 430-1 at 23–28].

As an initial matter, it is not readily apparent to the Court why these FTC materials would be relevant and therefore admissible. The FTC's position on the lawfulness of other reverse payments has no bearing on whether the settlement agreement here was unlawful, and the fact that the materials provide helpful background information on the pharmaceutical industry does

[4] Defendants' reliance on Matsushita Elec. Indus. Co. v. Zenith Radio Corp., [FWK 419-1 at 24; FWK 436-1 at 16], is misplaced. In that case, the Supreme Court evaluated the summary judgment standard in antitrust cases implicating § 1 of the Sherman Act. 475 U.S. 574, 576–77 (1986). In other words, the court was deciding the quantum of evidence an antitrust plaintiff must adduce to withstand a motion for summary judgment. Id. Here, the Court has already concluded that there is a genuine factual dispute as to the existence of the no-AG Agreement. What a plaintiff must do to advance to trial is a different question from what evidence a plaintiff may present at trial after having already survived a motion for summary judgment.

not make them relevant within the meaning of the Federal Rules of Evidence. See Fed. R. Evid. 401 (noting that "evidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action."). Even if all or some of the FTC materials were relevant, the Court would still exclude them. In Solodyn, Judge Casper dealt with a similar issue and ruled that although experts could rely on the materials, they could not be independently admitted into evidence. Court's Rulings on Various Motions In Limine, In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. 14-md-02503 (D. Mass. Mar. 8, 2018), ECF No. 1089. In reaching her conclusion, she noted that the materials contained opinions about contested issues including fostering competition, the harm to consumers from "pay-for-delay" agreements, and the effect of AGs on competition, and that the FTC materials, unlike the experts who relied on them, would not be subject to cross-examination. Id. Additionally, she precluded the defendant from introducing evidence of any inaction resulting from an investigation into the allegations at issue in that case because it could result in the jury putting undue weight on the opinion of the commission. Id. Judge Casper's approach was sound, and the Court will take the same one here. Accordingly, Plaintiffs will not be permitted to independently admit FTC materials into evidence nor will Defendants be permitted to introduce evidence regarding the FTC's decision not to pursue an enforcement action concerning the allegations underlying this case.

5. Defendants' Motion in Limine No. 5

Defendants move to preclude Plaintiffs from introducing any evidence that Professor Cima, who testified on behalf of Actavis in its patent litigation with Shire, and Professor Amiji, who testified on behalf of Teva in another patent suit, were involved in prior Intuniv-related patent litigation or arguing that Actavis "switched sides" regarding the validity or infringement

of the Intuniv patents. [FWK 418 at 1]. They argue that any probative value would be outweighed by the risk of misleading the jury into believing that Actavis has advanced inconsistent positions or that Professors Cima and Amiji are more credible or qualified than other expert witnesses. [FWK 419-1 at 33–35]. Plaintiffs maintain that the evidence is relevant and not unduly prejudicial. [FWK 430-1 at 28–31].

Given that Actavis will not be a party to this litigation when the case is tried, see [FWK 551; FWK 546], it is possible that this issue is moot. The Court notes that the most recent motion to disqualify Professors Cima and Amiji was filed by Actavis, not Shire. See [FWK 413]. If Shire wishes to advance this motion, it must do so in a motion of its own. If this issue is not moot, the Court encourages the parties to reach an agreement regarding the professors' testimony, including, perhaps, stipulating that they are qualified, which would obviate the need for specific testimony regarding their qualifications and experience, or agreeing that they will be allowed to refer to their experience in pharmaceutical patent litigation generally but without mentioning specific products or cases.

6. Defendants' Motion in Limine No. 6

Defendants move to keep Professors Cima and Amiji from relying on evidence that was not before Judge Andrews when attempting to predict his decision, claiming that such opinions would be irrelevant, confusing, and unduly prejudicial. [FWK 418 at 1; FWK 419-1 at 35–39].

The Court has already ruled on the scope of permissible testimony from Professors Cima and Amiji. See [FWK 525 at 29].

7. Defendants' Motion in Limine No. 7

Defendants seek to preclude Professor Cima from opining on secondary considerations of non-obviousness because he failed to timely disclose that opinion in either of his expert reports.

[FWK 418 at 2; FWK 419-1 at 39–41]. Plaintiffs respond that the opinion was properly disclosed. [FWK 430-1 at 35–36].

The principal purpose of Federal Rule of Civil Procedure 26(a)(2)'s expert disclosure requirement is to provide the opposing party with an opportunity to prepare for cross-examination and/or to obtain an expert of its own. See Chartier v. Brabender Technologie, Inc., No. 08-cv-40237, 2011 WL 4732940, at *7 (D. Mass. Oct. 5, 2011). Here, Defendants know what Professor Cima will testify to and have had ample opportunity to prepare cross-examination or retain a rebuttal expert. Although he indicated in his initial report that he was "not aware of any secondary considerations of nonobviousness," Professor Cima expressly reserved his right to respond to Defendants' experts' opinions on that topic. [FWK 428-4 at 52]. He then did so in his rebuttal report, by incorporating by reference an earlier report from the underlying patent litigation. [FWK 325-179 at 15–16]. Defendants can refer to that earlier report for Professor Cima's opinions and may cross-examine Professor Cima as to why he elected not to discuss secondary considerations in his opening report. Finally, by Plaintiffs' own admission, [FWK 430-1 at 35–36], Professor Cima is qualified to testify concerning only one secondary consideration, "teaching away," and will be so limited at trial.

8. Defendants' Motion in Limine No. 8

Defendants move to prevent Plaintiffs from offering opinions or argument that Judge Andrews would have issued a decision on the merits on or before May 31, 2013 and/or introducing evidence of judicial practice in patent cases after the settlement date. [FWK 418 at 2].

The Court has already ruled on Professor Thomas' timing-related testimony. See [FWK 525 at 24–25]. With respect to argument, Plaintiffs will be precluded from making such

arguments for the same reasons that Professor Thomas will be precluded from offering such testimony.

9. Defendants' Motion in Limine No. 9

Defendants move to preclude Professor Thomas from offering an opinion regarding whether Judge Andrews' opinion would have been upheld on appeal because such testimony is speculative and inadmissible. [FWK 418 at 2; FWK 419-1 at 45–49].

The Court has already ruled on this aspect of Professor Thomas' testimony. See [FWK 525 at 24].

10. Defendants' Motion in Limine No. 10

Defendants move to exclude evidence and arguments that denigrate the patent system as it would be irrelevant and prejudicial. [FWK 418 at 2; FWK 419-1 at 49–51]. More specifically, Defendants seek to prohibit Plaintiffs from introducing evidence or argument that: (1) the Patent & Trademark Office ("PTO") or its patent examiners are overburdened, incompetent, or error-prone; (2) the PTO issues too many patents; or (3) the PTO issues "bad" or "flawed" patents. [FWK 419-1 at 50]. Plaintiffs answer that the evidence they will seek to admit is factually accurate, relevant, and not unduly prejudicial. [FWK 430-1 at 43–46]. This motion is denied with leave to renew at trial.

General statements and statistics about the PTO's capacity and/or aptitude are, at most, marginally relevant to whether the particular patent at issue in this case was valid, and the Court is inclined to find that any relevance is substantially outweighed by a danger of confusing the issues and misleading the jury. See Fed. R. Evid. 403. Further, the fact that the Federal Circuit has acknowledged the PTO's resource constraints does not render testimony regarding such

constraints admissible at any trial implicating patents. Nonetheless, there may be instances when such testimony is more probative than prejudicial, depending on how the trial unfolds.

Accordingly, Plaintiffs may offer evidence and argument about the patent examination process in general and the prosecution history of the patent at issue in this case in particular. Plaintiffs are cautioned about evidence and argument concerning time constraints and other difficulties that patent examiners may face, and Defendants may renew their motion on those points at trial. Based on his experience, Professor Thomas may draw inferences from the prosecution history of the patent but may not speculate as to what the examiner thought or considered. See Abbot Biotech. Ltd. v. Centocor Ortho Biotech, Inc., No. 09-cv-40089, 2014 WL 733077, at *7–8 (D. Mass. Dec. 19, 2014). His testimony must be limited to "direct statements about the record, what it contains, and what it does not contain." Id. at *8.

11. Defendants' Motion in Limine No. 11

Defendants seek an order precluding Plaintiffs from imputing the views of "Old Actavis" regarding an at-risk launch to Actavis here, arguing that such testimony or argument would mislead and confuse the jury. [FWK 418 at 2; FWK 419-1 at 51–56]. Plaintiffs respond that Defendants' argument is a red herring and that Old Actavis' view of an at-risk launch is relevant because it was a reasonable company in Actavis' position. [FWK 430-1 at 46–51].

Given that Actavis will not be a party to this litigation when the case is tried, see [FWK 551; FWK 546], the confusion issues that Defendants raise may well be moot. If Shire wants to pursue this issue, it should file a revised motion that accounts for the absence of Actavis from this trial.

12. Defendants' Motion in Limine No. 12

Defendants move to exclude a May 2013 Actavis email. [FWK 418 at 2]. They argue that the email—between two Actavis employees, purportedly reflecting an understanding that Shire would not launch an AG during Actavis' 180-day exclusivity period—is inadmissible hearsay and cannot be attributed to Shire. [FWK 419-1 at 56–60]. Plaintiffs maintain that the email is admissible against both Actavis and Shire. [FWK 430-1 at 51–57].

Because Actavis will not be a party to this litigation when the case is tried, see [FWK 551; FWK 546], the Court is reluctant to speculate as to if, and through which witness, Plaintiffs intend to admit this email into evidence. The Court will therefore deny this motion with leave to renew at trial, at which time it will be better positioned to evaluate authenticity, foundation, and, if appropriate, whether there is an applicable hearsay exception.

13. Defendants' Motion in Limine No. 13

Defendants move to exclude evidence regarding RDC's bankruptcy proceedings. [FWK 418 at 2]. As discussed supra, Section II.A.22, the parties agree on this issue. No evidence or argument regarding bankruptcy and/or unrelated antitrust litigations involving the parties will be permitted.

14. Defendants' Motion in Limine No. 14

Defendants seek to prevent Plaintiffs from introducing evidence that Defendants tried to retain Dr. Fernandez. [FWK 418 at 2]. Based on the briefing, the parties have resolved this issue, see [FWK 430-1 at 58 (Plaintiffs agreeing not to reference Defendants' communications with Dr. Fernandez so long as Defendants do not challenge Dr. Fernandez's qualifications); FWK 436-1 at 34 (Defendants agreeing not to challenge Dr. Fernandez's qualifications)], and the motion is therefore moot.

15. Defendants' Motion in Limine No. 15

Defendants seek an order precluding Plaintiffs' counsel and witnesses from using pejorative and inflammatory terms to describe (1) Defendants or their alleged conduct, (2) the terms and negotiation of the settlement agreement, or (3) the pharmaceutical industry generally. [FWK 418 at 2; FWK 419-1 at 66]. Specifically, Defendants object to Plaintiffs' counsel and witnesses using terms such as "reverse payment," "kickback," "collude," "pay-for-delay," "conspirators," "monopoly profits," "profit sharing / splitting provision," "ill-gotten gains," "anticompetitive," "illegal," "Big Pharma," "big drug companies," "drug company's lawyers," and/or other similar terms because they are unduly prejudicial and could confuse and/or mislead the jury. [FWK 419-1 at 63–66]. Plaintiffs answer that the terms are accurate and will not unduly prejudice Defendants. [FWK 430-1 at 58–60].

As noted supra, Section II.A.9.e, litigants are generally afforded an opportunity to present their own theories of the case, including by choosing the language they use, and should not be prohibited from using terminology that opposing parties find unflattering. Even setting aside that general principle, some of the terms that Defendants object to are simply unobjectionable. For instance, antitrust plaintiffs asserting § 1 claims under the Sherman Act cannot be expected to conduct a trial without using the terms "anticompetitive," "collude," "conspiracy," and "conspirators." Further, like Judge Young in the Nexium antitrust case, the Court is untroubled by terms like "pay-for-delay" and "reverse payment." See Transcript from Charging Conference 35:17–19, In re Nexium (Esomeprazole) Antitrust Litig., No. 12-md-02409 (D. Mass. Oct. 20, 2014), ECF No. 1100. As to most of the remaining terms, given that the Court will instruct the jury on the difference between argument and evidence and, if requested, would be willing to provide a specific instruction regarding the difference between civil and criminal antitrust

liability, the Court believes that the terms are not unduly prejudicial and will not, at this time, bar Plaintiffs' counsel and witnesses from using them. If such terminology becomes a distraction at trial or the Court comes to believe such language is having an undue influence on the jury or being used to improperly inflame, the Court will respond accordingly. The Court will be particularly watchful about the use of terms like "bribe" and "kickback" and will not allow unflattering or pejorative characterizations of any counsel. Additionally, given that the purpose of trial is to determine liability, Plaintiffs' counsel may offer their view that Defendants' conduct was "illegal" or "unlawful," but Plaintiffs' witnesses should not describe Defendants' conduct as such without adequate qualification or foundation. Finally, whether Defendants acted "morally" or "ethically" is beyond the scope of trial, and Plaintiffs are therefore precluded from describing Defendants' conduct as "immoral," "amoral," or "unethical."

16. Defendants' Motion in Limine No. 16

Defendants ask that Plaintiffs not be allowed to appeal to jurors' self-interest as consumers or taxpayers. [FWK 418 at 2]. Plaintiffs represent that they do not intend to "offer evidence or argument designed to appeal to popular antipathy toward pharmaceutical companies unconnected to the alleged abuses here," but maintain that evidence concerning how the pharmaceutical industry functions, such as the differences in pricing between brand-name and generic drugs, is essential to their case. [FWK 430-1 at 60–62].

Given the difficulty in prospectively ruling on whether a given piece of evidence or argument's probative value is substantially outweighed by its tendency to prejudice the opposing party or mislead or confuse the jury, the Court will defer ruling on specific arguments, exhibits, or testimony until trial. That said, Plaintiffs will not be permitted to argue or suggest that (1) because Defendants are involved in the pharmaceutical industry, they have engaged in

wrongdoing or are otherwise "bad" or "greedy," (2) the pharmaceutical industry is broken, flawed, or otherwise deficient, (3) drug prices are, in general, "too high," (4) jurors will be better off as consumers or taxpayers if they find Defendants liable (or worse off as consumers or taxpayers if they do not), or (5) society would benefit as a whole from a ruling in Plaintiffs' favor. Plaintiffs will, however, be allowed to elicit proper testimony concerning how the pharmaceutical industry functions, including the differences in pricing between brand-name and generic drugs, subject to standard trial objections by Defendants.

17. Defendants' Motion in Limine No. 17

Defendants object to Plaintiffs being allowed an adverse inference based on the absence of defense witnesses. [FWK 418 at 2]. Defendants argue that because many of their witnesses are no longer under their control and are also outside the Court's subpoena power, they should not be subjected to an adverse inference if such witnesses do not appear at trial. [FWK 419-1 at 67–68].

As Plaintiffs appear to concede, see [FWK 430-1 at 62], whether an adverse inference is appropriate with respect to a given witness depends, at least in part, on whether that witness is within the other party's power or control. That is a fact-based determination that will have to be made on a witness-by-witness basis. Because the Court does not have the facts necessary to make such determinations at this stage and, given Defendants' representation that they will "work cooperatively to make witnesses available," the Court denies this motion with leave to renew at trial if warranted.

18. Defendants' Motion in Limine No. 18

Defendants move to prevent Plaintiffs from referring to the compensation structure of current or former employee witnesses. [FWK 418 at 2]. Because the briefing reflects that the

parties have resolved the issue, see [FWK 430-1 at 63–64 (Plaintiffs agreeing not to offer evidence or argument concerning compensation of Defendants' current or former employees as long as Defendants refrain from the same with respect to Plaintiffs' employee witnesses); FWK 436-1 at 37 (Defendants' agreeing to Plaintiffs' terms)], the motion is moot.

19. Defendants' Motion in Limine No. 19

Defendants seek to preclude Plaintiffs from referring to alleged anticompetitive conduct involving other products, including unrelated proceedings, lawsuits, and settlements involving such products. [FWK 418 at 2]. They argue that such evidence or argument would be irrelevant, unduly prejudicial, and improper character evidence. [FWK 419-1 at 70–73]. Plaintiffs maintain that they will not introduce any evidence to show a propensity for misconduct, but that evidence of other products may be relevant to other issues and the Court should defer ruling on the issue until trial. [FWK 430-1 at 64–66].

As Plaintiffs acknowledge, [FWK 430-1 at 64], propensity evidence is inappropriate, and Plaintiffs will not be permitted to make argument or offer evidence at trial to the effect that because Defendants have been accused of anticompetitive conduct with respect to other drugs, they have engaged in anticompetitive conduct here. Beyond that, the Court will defer ruling on the admissibility of evidence related to other drugs (e.g., Lialda) until trial. Plaintiffs have advanced plausible explanations for why such evidence may be relevant, and the Court will weigh relevance against potential prejudice as the issue arises at trial.

20. Defendants' Motion in Limine No. 20

Defendants move to exclude legal opinions that may be offered by Plaintiffs' witnesses. [FWK 418 at 2]. This is based on their belief that Plaintiffs' experts Messrs. Upadhye and

Johnson will impermissibly testify to their own legal opinions on issues in this case, including the ultimate issue of liability. [FWK 419-1 at 73].

The Court has already ruled on the scope of Messrs. Upadhye's and Johnson's testimony. See [FWK 525 at 46–54].

21. Defendants' Motion in Limine No. 21

Defendants seek an order precluding Plaintiffs from disclosing document confidentiality or privilege designations to the jury, claiming that such designations are irrelevant and prejudicial. [FWK 418 at 2; FWK 419-1 at 74–76]. Plaintiffs do not object to the removal of confidentiality designations applied *during the litigation* but do object to the removal of any designations that pre-date the litigation. [FWK 430-1 at 68–70].

Based on the parties' agreement, see [FWK 436-1 at 39], neither party will be permitted to refer to confidentiality designations that have been applied to documents during this litigation and such designations will be removed before documents are displayed or submitted to the jury. With respect to designations pre-dating the litigation (e.g., emails with a "Privileged – Prepared at the Request of Counsel" header), although Plaintiffs will not be permitted to draw an inference of bad faith based solely on the assertion of attorney-client privilege, the Court will not require documents to be redacted in this manner. The context in which the documents were created may be relevant to a key issue in this case (i.e., whether Shire's evaluation of an AG launch was legitimate) and to alter the documents to strip away part of that context would be inappropriate. The Court will consider an appropriate jury instruction if asked to provide one.

22. Defendants' Motion in Limine No. 22

Defendants move to prevent Plaintiffs from referring to or asking questions about information that Defendants' experts are bound not to disclose because of pre-existing

confidentiality obligations. [FWK 418 at 2]. Plaintiffs maintain that without additional details (e.g., which specific information Defendants argue is confidential, the contractual bases for asserting confidentiality, etc.), they cannot adequately respond to Defendants' motion. [FWK 430-1 at 70–72]. Defendants have offered to provide more detail. See [FWK 419-1 at 78 n.110; FWK 436-1 at 41 n.114].

The Court too requires more information to rule on this motion and will therefore deny it with leave to renew if the parties cannot resolve the issue on their own.

C. FWK 416: Defendants' Additional Motions in Limine

In a separate filing, Defendants make two additional motions. [FWK 416].

1. Defendants' Motion in Limine No. 23

Defendants move to keep Plaintiffs from attempting to use Defendants' invocation of the attorney-client privilege to draw negative inferences in front of the jury (including by referencing Defendants' privilege log). [FWK 416 at 2]. Plaintiffs respond that Defendants' motion is overbroad and premature. [FWK 425-1 at 6–12].

Ruling on Defendants' request at this stage would be premature. That said, for guidance, the Court notes that, as a general matter, the fact of legal consultation is not privileged. See Humphreys, Hutcheson and Moseley v. Donovan, 755 F.2d 1211, 1219 (6th Cir. 1985). Accordingly, Plaintiffs will be permitted to ask questions designed to elicit the fact that Defendants consulted with attorneys so long as they do not seek to elicit the substance of those communications. The Court will also not preclude Plaintiffs from making appropriate use of a privilege log, including to refresh a witness's recollection or to impeach a witness, so long as they do not seek to elicit privileged information. Finally, Plaintiffs may adduce evidence that Defendants consulted with counsel but cannot argue or imply that such consultation or the fact of

a privilege log necessarily reflects misconduct. If circumstances warrant, the Court will consider instructing the jury on the attorney-client privilege.

2. Defendants' Motion in Limine No. 24

Defendants seek an order preventing Plaintiffs from arguing that Defendants have waived attorney-client privilege based on the fact that Defendants or their counsel have made generalized statements to each other or the public about various aspects of the patent litigation or their settlement. [FWK 416 at 2]. Plaintiffs respond that they are not currently seeking a finding of waiver. [FWK 425-1 at 12–14]. The motion is therefore denied as moot.

III. CONCLUSION

Accordingly, for the reasons stated above, each motion in limine, [FWK 412; FWK 416; FWK 418; Picone 302; Picone 304], is GRANTED in part and DENIED in part.

SO ORDERED.

March 3, 2021

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE